miraDry Implements AssurX Quality Management and Regulatory Compliance Software

AssurX Platform will Automate and Standardize Quality Operations Across Quality Operations

MORGAN HILL, CALIFORNIA, UNITED STATES, March 31, 2022 /EINPresswire.com/ -- AssurX, Inc. (AssurX), a leader in quality management software and regulatory compliance software, announced today that miraDry®, a leading provider of treatment for Primary Axillary Hyperhidrosis (excessive sweating) has implemented the AssurX platform to automate their quality and compliance management processes.

miraDry is headquartered in the US, and treatments are now available in more than 50 countries worldwide. It was the first device to receive FDA clearance for using electromagnetic energy to combat excessive sweating, but the technology has been used safely in other areas of medicine for years, including applications for cardiology, cosmetics, urology, and oncology.

miraDry recently implemented the AssurX quality management system (QMS) to manage complaint handling, CAPA assessments, and adverse event reporting requirements. "Having used AssurX before, I was already confident that the software would help us modernize our complaint handling process and meet GMP compliance requirements," explained Irene Mo, Vice President, Regulatory, Quality & Clinical, miraDry.

AssurX replaced miraDry's formerly disconnected complaint handling and adverse event reporting with an automated system that processes, qualifies and tracks complaints from intake to closure. In addition, the system populates and submits MedWatch reports, and all acknowledgments from the FDA are received in real time. AssurX's ease of configuration allows companies to rapidly adapt to changing business and regulatory climates.

The company is planning to systematically integrate additional quality processes, including full integration to launch CAPAs directly from assessments within the complaint record.

"AssurX is highly configurable and very flexible," added Mo. "AssurX empowers its customers to build and support unlimited processes that can be modified with no coding. It's powerful yet simple, and that's a big plus for onboarding users. We were able to quickly identify and close gaps that have improved performance results."

"We're pleased to be the quality management software of choice for miraDry," said Tamar June, President and CEO, AssurX. "Our true platform approach to QMS delivery is unique, as it doesn't require intervention each time a process or "module" is added. AssurX enables customers to build enterprise quality ecosystems with as much or as little support as they need."

Quality and compliance in the medical device industry requires constant adaption to change. AssurX is designed to transform with regulatory, industry, and business requirements to help customers create quality systems that accelerate building safer products faster.

ABOUT MIRADRY

miraDry was the first device to receive FDA clearance for using electromagnetic energy to combat excessive sweating. It provides a permanent solution for underarm sweating, also known as Primary Axillary Hyperhidrosis. The miraDry procedure is quick and non-invasive. For more information, visit www.miradry.com.

ABOUT ASSURX INC.
With decades of expertise built into our quality management and regulatory compliance software, the AssurX Quality Management Software Platform helps companies maintain quality and compliance standards, streamline workflow and better manage any enterprise. Our configurable software and understanding of users' needs produce a unique system that easily adapts as a customer's business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant. To learn more, visit: www.assurx.com.

AssurX Marketing
AssurX
+1 408-778-1376 ext. 797
marketing@assurx.com